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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,698	12/05/2003	Presley Hays	10225-003003	9981

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FISH & RICHARDSON, PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

PATEL, KANJIBHAI B

ART UNIT	PAPER NUMBER
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2624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/728,698

Applicant(s)

HAYS ET AL.

Examiner

Kanji Patel

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/5/03, 9/1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 12/05/03 and 9/01/04 are being considered by the examiner.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,671,393 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because.

- Claims 1 and 11-12 of the instant application and claims 1 and 11 of the Patent recite common subject matter (limitations (a) to limitation (j) in both

claims are exactly identical. Only a slight wording difference in limitation of step (k) of the instant claims 1 and 11-12 is that it uses the phrase "determine the optical density of the protein" while the Patent claims 1 and 11 in step (k) uses the phrase "determining a protein level" which is an obvious variation of the optical density and does not change the scope of the invention. Therefore, the claimed invention in instant claims is not patentably distinct from the invention claimed in the Patent claims.

- Whereby claim 1, which recites the open ended transitional phrase "comprising", does not preclude the additional elements recited by claim 1, and
- Whereby the limitations of the instant claims 1 and 11-12 are fully anticipated by the Patent claims 1 and 11, and anticipation is "the ultimate or epitome of obviousness" (*In re Kalm*, 154 USPQ 10 (CCPA 1967), also *In re Dailey*, 178 USPQ 293 (CCPA 1973) and *In re Pearson*, 181 USPQ 641 (CCPA 1974)).
- Furthermore dependent claims 2-10 of the instant application are exactly identical to dependent claims 2-10 of the Patent claims and therefore they are also not patentably distinct from the Patent claims.

3. **Claims 1-12** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4, 6-7, 9, 11 and 13-16 of U.S. Patent No. 6,330,349 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because.

- Claims 1 and 11-12 of the instant application and claims 1 and 16 of the Patent recite common subject matter;
- Whereby claim 1 and 11-12 which recite the open ended transitional phrase "comprising", does not preclude the additional elements recited by claims 1 and 16 of the Patent; and
- Whereby the limitations of the instant claims 1 and 11-12 are fully anticipated by the Patent claims 1 and 11, and anticipation is "the ultimate or epitome of obviousness" (*In re Kalm*, 154 USPQ 10 (CCPA 1967), also *In re Dailey*, 178 USPQ 293 (CCPA 1973) and *In re Pearson*, 181 USPQ 641 (CCPA 1974)).
- Furthermore dependent claims 2-10 of the instant application correspond to dependent claims 3-4, 6-7, 9, 11, 13-15 of the Patent claims and therefore they are also not patentably distinct from the Patent claims.

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Contact Information

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kanji Patel whose telephone number is (571) 272-7454. The examiner can normally be reached on Monday to Thursday from 8 a.m. to 6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lillis Eileen can be reached on (571) 272-6928 The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kanji Patel
Art Unit 2624
4/15/07


KANJIBHAI PATEL
PRIMARY EXAMINER